



August 08, 2001

*"Major" finding
not included in
this cover letter.*

Mr. Anthony Medrano
U.S EPA Region VIII/TMS-Q
Supervisor Environmental Protection Specialist
999 18TH Street, Suite 500
Denver, CO 80202

RE: RAC 68-W7-0037

SUBJECT: **Washington Group International, Inc. Data Usability Assessment in Relation to the Quality Assurance Audit Report of Paragon Analytics, Inc.**

Dear Mr. Medrano:

Pursuant to the Paragon Analytics, Inc. audit findings, the audit team would like to address the compliance and usability of the data set from the RAC sampling events that have occurred to date. In scope and complexity, the audit was comprehensive and focused on the overall QA programs and compliance to the client-specific RAC project requirements. Many of the conditions observed during the audit, although significant, do not directly affect the data usability based on the validated quality assurance documentation associated with this data and the following rationale specific to each audit finding report (AFR).

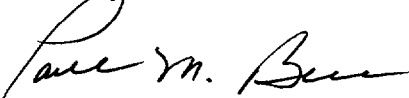
- **AFR No. 1-** Paragon's LQAP and two SOPs were past the required revision dates. It should be noted that upon approval of Paragon as the primary laboratory following the bidding process, the revisions of the LQAP and SOPs were updated and current. The minor changes needed in revisions (i.e. waste disposal, lab safety and current practices) were determined to be standard maintenance of the written QA Program and do not affect the protocols for sample analysis in the lab. The audit team observed that the analytical methods were being followed in the laboratory, and has confirmed method compliance through WGI's data validation.
- **AFR No. 2-** Lab training records were found to be missing or incomplete. During the audit, the laboratory was in the process of reorganizing and restructuring training records. Department-specific training records such as initial demonstrations of proficiency exist in the LIMS database but have not been organized and placed in each analyst's file. The complete files for key personnel were observed to have all documents included. Paragon is currently developing a database interface that will supplement and/or replace the checklists used in order to track and manage the files more efficiently and effectively while the physical reorganization takes place.
- **AFR No. 3-** The laboratory's in-house control limits have not been updated semi-annually. WGI will now require Paragon to provide documentation of quarterly control charting whether the limits change considerably or not. However, it should be noted that project-specific limits have been used for the majority of samples run under the RAC projects as specified in the project specific QAPP (VB/I-70 samples). Where project-specific limits were not specified, quality control results were compared against the limits specified in the EPA National Functional Guidelines for Inorganic and Organic Data Review (Intermountain Waste Oil Refinery samples). Where the Guidelines defer to in-house laboratory limits, Paragon's controls limits were applied following review to confirm that the limits were reasonable.

- **AFR No. 4-** Certain out-of-service lab instruments/equipment were missing "tag-out" labels, but were not being used by any of the analysts. Paragon personnel placed tags on the two pieces of equipment noted in the audit report on 5/8/01 and searched the lab for any other existing instruments or equipment needing to be tagged and segregated (none were found). The missing tag-out labels did not impact any of WGI's data sets based on review of the raw data, which specifies the instrument identification.
- **AFR No. 5-** Some of the lab's Non-Conformance Reports (NCRs) were missing complete documentation of follow-up and closure by the QA department. None of the RAC data set provided to date has had a NCR issued or generated for the data package. The audit team agrees with Paragon that the NCR process is effective as currently designed if fully implemented and closed out for every report. This Audit Finding was issued to Paragon to ensure that a fully completed report is filed and retained in the lab's records, which includes documentation of disposition, corrective action follow-up and proper closure. Every NCR reviewed showed that the project manager and/or the client were notified for the issue identified. A review of Paragon's NCR log indicated that no NCR's were issued against or correlating to methods run for or samples provided by WGI.
- **AFR No. 6 and 7-** Internal QA audits were not conducted monthly with documentation in the form of a checklist along with follow-ups and formal closure. It should be noted that there are no method-specific requirements for internal QA audits. The audit team saw evidence that Paragon has recently hosted a large number of external audits. Paragon stated that they also count external audits as a monthly QA audit in their audit scheduling. Paragon will be revising the internal QA audit schedule and SOP 937 to reflect the current lab practice and checklists used. The audit team reviewed numerous internal and external audit documents showing corrective actions taking place and successful audit closure.

In summary, the deficiencies identified in the audit report were programmatic in nature and were not data-quality affecting. WGI concludes that Paragon Analytics has provided defensible data that meet the project completeness objectives with none of the sample data being rejected. WGI's data validation performed on level 4 raw data packages has verified compliance to the method-specific and project-specific requirements and found no systematic bias. The audit team concludes that the data provided by Paragon is compliant and usable.

Should you have any questions regarding this assessment, please contact me at (303) 843-3204.

Sincerely,



Paul M. Bell
Quality Assurance Manager

Cc: J. Powell
B. Lavelle
L. Lloyd
M. Goldade